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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,853	12/14/2004	Satoshi Yonehara	10873.1578USWO	9018

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EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,853	YONEHARA ET AL.	
	Examiner	Art Unit	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 6-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 6-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3, and 6-20 are pending in this application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

All objections and rejections not repeated in the instant Action have been withdrawn due to Applicant's response to the previous Action.

Terminal Disclaimer

The terminal disclaimer filed on 03/13/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/521,234 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "by causing" in Claim 10 is deemed indefinite as it is not clear at which point that fructosyl amino acid oxidase has been added to the reaction mixture. Claim 11 is rejected as being dependent on Claim 10.

Applicants arguments pertaining solely to the previous rejections are rendered moot in light of the new rejections set forth below:

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3 and 6-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant states in Claim 1 that the method is for measuring an analyte in a sample containing hemoglobin or a "hemoglobin degradation product", however it is unclear what is meant by this term and it is not clearly defined in the instant specification. For example, hemoglobin degradation products can encompass Carbon Dioxide, oxygen, Iron, biliverdin, and two α and β chains. Claims 3 and 6-20 are rejected for being dependent on Claim 1.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 rejected under 35 U.S.C. 102(b) as being anticipated by Ouyang *et al.* (5,902,731).

Ouyang teaches a method for measuring ketone bodies in blood samples by using a redox reaction, wherein prior to the redox reaction sodium nitrite is added to the sample so as to eliminate the influence of hemoglobin contained in the sample (Column 5, Lines 42-47) forming an oxidizing (NAD+) and reducing substance (NADH) derived

from the analyte (Figure 4) and measuring the amount of the formed substance derived from the analyte by the redox reaction and determining the amount of analyte from the measurement value indicating the amount of NADH (Column 5, Lines 47-53).

Ouyang teaches a method wherein the redox reaction is a color development reaction involving reducing an oxidizing substance derived from the analyte and oxidizing a substrate wherein the amount of color developed is measured by measuring absorbance (Figure 4 and Column 5, Lines 47-53).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3 and 6-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouyang *et al.* (5,902,731) in view of Komori *et al.* (2002/0025546 A1).

The teachings of Ouyang were discussed above.

Ouyang does not teach a method wherein both a sulfur containing compound and a nitrogen containing compound are added to the sample, the redox reaction is a color development reaction using the oxidase peroxidase, or the oxidizing substance is hydrogen peroxide.

Ouyang does not teach a method wherein the analyte is a glycated protein, peptide, amino acid, or wherein the glycated protein is glycated hemoglobin, or wherein the sample is obtained by hemolyzing erythrocytes.

Ouyang does not teach the use the color developing substrates N-(carboxylmethylaminocarbonyl)-4,4'-bis(dimethylamino)diphenylamine sodium salt, a combination of Trinder's reagent and 4-aminoantipyrine, N,N,N',N',N",N",-hexa(3-sulfopropyl)-4,4',4"-triaminotriphenylmethane hexasodium salt, or N,N,N',N',N",N",-hexa(2-hydroxy-3-sulfopropyl)-4,4',4"-triaminotriphenylmethane hexasodium salt, or 10-

(carboxymethylaminocarbonyl)3,7-bis(dimethylamino)phenothiazine sodium salt, or 10-(methylaminocarbony)3,7-bis(dimthylamino) phenothizine sodium salt.

Ouyang does not teach the addition of a sulfonic acid compound to a sample so that its concentration is between 0.05-200mmol/L when a concentration of blood cells in the sample is 1% by volume.

Ouyang does not teach the addition of the nitro compound to a sample so that its concentration is between 0.05-500mmol/L when a concentration of blood cells is 1% by volume.

Ouyang does not teach the addition of a sulfonic acid compound and a nitro compound to a sample so the their respective concentrations are 0.05 to 200mmmol/L and 0.05 to 250mmol/L when a concentration of blood cells in the sample is 1% by volume.

Komori *et al.* teaches a method for measuring analyte in a sample containing hemoglobin or hemoglobin degradation products by using a redox reaction, comprising adding a nitro compound to the sample to eliminate the influence of the reducing substances contained in the sample, forming an a reducing substance or an oxidizing substance derived from the analyte, and determining the amount of the from the quantity of the formed substance. (Page 1,Column 1, Lines 4-18)

Komori *et al.* teaches adding both the nitro compound WST-3 and a surfactant to the sample. (Page 4, Column 1, Lines 1-20)

Komori *et al.* teaches that the redox reaction is a color development reaction caused by reducing the oxidizing substance derived from the analyte (hydrogen peroxide) and oxidizing a substrate that develops color by oxidation using an oxidase (peroxidase), wherein the amount of oxidizing substance developed is quantified by the degree of color development. (Page 12, Column 2, Claims 13 and 14)

Komori *et al.* teaches that the degree of color development is measured by measuring at a wavelength for detecting the substrate. (Page 5, Column 1, Lines 4-11)

Komori *et al.* teaches that the analyte can be glycated protein, glycated peptides, or glycated amino acids and hydrogen peroxide is formed as the oxidizing substance derived from the analyte by causing a fructosyl amino acid oxidase (FAOD) to act on the analyte, (Page 3, Column 1, Lines 12-19) and the addition of a surfactant and a nitro compound to the sample before causing the FAOD to act on the analyte. (Page 4, Column 1 Lines 5-16 and Column 2, Lines 18-21)

Komori *et al.* teaches the use of the above steps with a color developing substrate N-(carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino)diphenylamine

sodium salt, a combination of Trinder's reagent and 4-aminoantipyrine (Page 4, Column 2, Lines 39-43)

Komori *et al.* teaches the glycated protein can be glycated hemoglobin and the hemolyzed sample is obtained by hemolyzing erythrocytes (Page 3, Column 1, Lines 3-11)

Komori *et al.* teaches the addition of a surfactant to a sample, the surfactant concentration between 0.01 to 5% by weight, (Page 4, Column 1, Lines 13-15) and the addition of the nitro compound to a sample so that its concentration is between 0.4 to 200mmol/L when the concentration of blood cells in the sample is from 1-10% by volume. (Page 4, Column 1, Lines 19-30)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the method for eliminating the influence of hemoglobin in a method for measuring an analyte in a sample containing hemoglobin as taught by Ouyang with the method for measuring an analyte in a sample as taught by Komori because it was known in the art at the time of invention that free hemoglobin can non-enzymatically reduce certain color developing substrates prior to reaction which can interfere or skew the experimental results. One of ordinary skill in the art at the time of the invention would have been motivated to combine the two methods in order to remove the potentially interfering presence of the free hemoglobin prior to the redox reaction in order to have the most accurate results. There would have been a reasonable

expectation of success in combining the methods since both are drawn to similar methods of analyzing analytes found in blood through the use of oxidation/reduction reactions.

Although Komori *et al.* does not teach the color developing substrates of Claim 13, it is deemed that the 10-(carboxymethylaminocarbonyl)3,7-bis(dimethylamino) phenothiazine sodium salt and 10-(carboxymethyl-4-benzaminocarbonyl)3,7-bis(dimethylamino) phenothiazine sodium salt are obvious variants of N-(carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino) diphenylamine sodium salt found in Claim 12. The ordinary artisan would have had a reasonable expectation that the 10-(carboxymethyl...) compounds would have acted as functional equivalent color developing substrates to N-(carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino) diphenylamine sodium salt.

With regard to the concentrations not taught by Komori *et al.* the MPEP states:

"Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")"

One of ordinary skill in the art at the time of the instant invention would have been motivated to experiment with the addition of the nitro compound and the sulfonic acid compound singly, and in conjunction, in order to test for negative results caused by an individual component before the attempting of the experiment using the two compounds simultaneously. The ordinary artisan would also have been motivated to adjust the concentrations of the compounds in order to optimize the experiment and achieve the best possible results.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence or evidence to the contrary.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

04/30/06